Amendments to the Claims

This listing of claims will replace all prior versions and listings of claims in the application.

1-76. (cancelled).

77. (currently amended) A method for preparing a sterile pharmaceutical composition of a steroid comprising:

(i) dissolving a non-sterile steroid in a solvent to yield a solution of the steroid,

(ii) filtering the solution to yield a sterile solution,

(iii) combining the sterile solution with sterile water to form a suspension,

(iv) optionally removing all or part of the solvent,

(v) treating the sterile suspension of (iii) or (iv) to obtain a particle size distribution having a mass median diameter less than 10 μm,

(vi) under sterile conditions combining the suspension with a pharmaceutically acceptable carrier to yield a sterile pharmaceutical composition comprising a suspension of the steroid having a mass median diameter less than 10 μm, and

(vii) storing the sterile pharmaceutical composition in sterile containers.

78. (previously presented) The method of claim 77, wherein the non-sterile steroid is a powder.

79. (previously presented) The method of claim 78, wherein the powder is a

micronized powder.

80. (previously presented) The method of claim 77, wherein the steroid is budesonide.

81. (cancelled).

82. (previously presented) The method of claim 77, wherein the solvent comprises an alcohol.

83. (previously presented) The method of claim 77, wherein the solvent comprises a Class 3 solvent.

84. (previously presented) The method of claim 77, wherein the solvent comprises a Class 2 solvent.

85. (previously presented) The method of claim 77, comprising combining solvent with the steroid at a temperature from 20 °C below the boiling point of the solvent up to its boiling point.

86. (previously presented) The method of claim 85, wherein the solvent is at reflux.

87. (previously presented) The method of claim 77, comprising removing solvent under reduced pressure.

88. (previously presented) The method of claim 77, comprising removing solvent at atmospheric pressure.

89. (previously presented) The method of claim 77, comprising filtering the solution through a filter having a pore size of 0.2 μm or less.

90. (previously presented) The method of claim 77, wherein the sterile water contains a surfactant.

91. (previously presented) The method of claim 77, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 1-5 μm.

92. (previously presented) The method of claim 91, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 2-3 μm.

93. (previously presented) The method of claim 77, comprising storing the sterile composition in sterile ampoules.

94. (currently amended) A method for preparing a sterile suspension of budesonide, comprising:

(i) dissolving non-sterile budesonide in a solvent to yield a budesonide solution,

(ii) filtering the solution to yield a sterile solution,

(iii) combining the sterile solution with sterile water to form a suspension of budesonide,

(iv) optionally removing all or part of the solvent,

(v) treating the sterile suspension of (iii) or (iv) to obtain a particle size distribution having a mass median diameter less than 10 μm,

(vi) under sterile conditions combining the suspension with a pharmaceutically acceptable carrier to yield a sterile pharmaceutical composition comprising the suspension of budesonide having a mass median diameter less than 10 μm, and

(vii) storing the sterile pharmaceutical composition in sterile containers.

95. (previously presented) The method of claim 94, wherein the solvent comprises an alcohol.

96. (previously presented) The method of claim 94, comprising filtering the solution through a filter having a pore size of 0.2 μm or less.

97. (previously presented) The method of claim 96, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 1-5 μm.

98. (previously presented) The method of claim 96, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 2-3 μm.

99.-106. (cancelled).